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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,034	11/24/2003	T. Douglas Mast	END-5042	4797

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/721,034	Applicant(s) MAST, T. DOUGLAS	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

Claims 1 –4, 9- 10, 16 – 19, 23 – 24, 30 are again rejected under 35 U.S.C. 102(b) as being anticipated by Okazaki (US5005580) or in the alternative as obvious based upon Okazaki in view of Dory (US5354258, of record). Okazaki teaches receiving ultrasound imaging signals (which are time varying signals insofar as they carry information and are derived from the RF carrier frequency of the ultrasound) during first and second time periods into 20a with processing and subtraction therebetween in 20b such that a subtraction image 26 of Fig. 6 is formed which image tracks discrete increments of medical therapy by kidney stone or calculus destruction including through the completion of the treatment, see col. 5 line 46 – col. 6 line 2. The context indicates that the method is practiced all the way from a baseline image of a treated region in its anatomic surroundment prior to treatment through just sufficient completion of treatment as determined from the succession of differential images. In the alternative, Dory makes clear that subtraction images may be iteratively obtained on a very short time base so as to be time-varying in order to monitor the course of treatment particularly when the treatment is causing rapid irreversible changes to the body. (Claims 1 –4, 9 – 10, 16 – 19, 23 - 24)

Such paired images are subtracted in an iteration which incrementally tracks treatment during its course. (claim 30).

Claims 1 – 4, 9 – 10, 16 – 19, 23 – 24, 30 are again rejected under 35 U.S.C. 102(e) as being anticipated by Lizzi et al (US6533726) or in the alternative as

obvious based upon Lizzi et al in view of Dory (US5354258, of record) as the latter is applied above. Lizzi et al in and of itself teaches receiving (time-varying as explained above) ultrasound imaging signals (Fig. 3 elements 310, 320, 330) during first and second and third time periods, and processing and subtracting the signals (340, 345) and generating an indication therefrom about the effect of the medical diathermy treatment in causing transitory or permanent tissue changes within the anatomic surroundment up to and including treatment termination and subsequent to an initial baseline reading. (Claim 1 – 4, 9 – 10, 16 – 19, 23 - 24).

Again, such paired images are subtracted in an iteration which incrementally tracks treatment during its course. (Claim 30).

Claim Rejections - 35 USC § 103,

Claim 5 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim1 above, or further in view of Dory, and further in view of Cain et al (US5590657). Whereas the former are silent as to motion compensation, it would have been obvious in view of the latter cols. 5-6 to compensate for phase aberration effects by a phase compensation function in order to re-focus the ultrasound imaging or treatment on the desired target volume in the event of movement within the target area. (Claim 5).

Claims 6-7, 11- 12, 20-21 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim1 above, and further in view of Dory (US5354258). Whereas the former are silent as to output scaling, it would have been obvious in view of the latter to perform scaling by element 74 on the

ultrasound difference image signal (output of 7) in relation to the initial image signal S2 , Since Dory is also tracking the differential tissue image as representing the progress of the treatment and scaling allows blending with the very initial anatomic or B-mode image as a second image type so that the absolute progress of the therapy can be tracked. (Claims 6, 11 - 12, 20).

The use of power scaling would have been obvious since Lizzi et al is concerned with attenuation changes in the tissue which is a power measurement (see col. 5 top) ; also Dory col. 5 lines 55-68 is concerned with power absorption by tissues.(Claims 7, 21).

Claims 8, 22 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al, or further in view of Dory, as applied to claim 1 above, and further in view of Geiser et al (US6106470). The former are silent as to spatial filtering. However it would have been obvious in view of the latter to provide at least some spatial filtering in post-processing an image in general for display in order to reduce graininess by using local average values. (Claim 8).

Claims 13- 15 and 25 – 29 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al, or further in view of Dory as applied to claim 1 above, and further in view of both Dory as applied with respect to scaling of the difference signal (claim 6) and also Geiser et al as applied with respect to spatial filtering (Claim 8) above, which evidence that both of these features were known in association with ultrasound monitoring of medical treatment of in association with general anatomic ultrasound imaging.. (Claims 13, 25, 28 - 29).

In both of the base references both a first and second image may be received after the initial treatment as the image differencing system iteratively advances during treatment increments, in essence a repeating of the claim 2 argument supra.. (Claims 14, 26).

The base argument against claim 3 that the iteration of differencing proceeds up to the final treatment as a viewing tool of its completion applies here (Claims 15, 27).

Claims 31- 32 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al, or further in view of Dory as applied to claim 30 above, and further in view of Fujimoto et al (US6540700). Whereas the former are silent as to the use of signal averaging, it would have been obvious in view of the latter to use signal averages, see col. 18 line 60 – col. 19 line 4 as well as col. 20 lines 12 – 23 since this permits small variations in signal levels due to noise to average out such that a small-difference circumstance as is measured during tissue treatment may be more accurately represented. (Claim 31).

Such averaging would be understood to be a cumulative summation and scaling because one cannot multiply the resulting brightness gradation of the video display. (Claim 32).

Response to Arguments

Applicants' arguments are not considered to be persuasive insofar as technically any signal including an imaging signal must be time-varying in order to convey information. More importantly, Dory evidences that a time-varying difference signal

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must be used when one is dynamically tracking therapeutic tissue changes over a very short time-frame.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

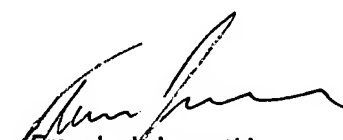
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Biegeleisen-Knight (US5148809) is cited as providing an ultrasound difference-transition image of the cardiac wall; Ema (US5095906) produces a time-varying image inter alia for diagnostic ultrasound image storage control; Dory 5150711 is cited to complete the record.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

07082005


Francis J. Jaworski
Primary Examiner